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10/594,181

11/27/2007

David G. Burton

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WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP
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EXAMINER

KENNEDY, JOSHUA T

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,181	Applicant(s) BURTON ET AL.	
	Examiner JOSHUA T. KENNEDY	Art Unit 3679	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4 and 6-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4 and 6-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner's note: In light of Applicants response filed 6/23/2009, Examiner has found the Applicants arguments with regards to the finality being premature because the Section 112 rejection was not necessitated by amendment to be persuasive. Accordingly, the finality of the previous rejection mailed 3/23/2009 has been withdrawn and the amendment filed 6/23/2009 has been entered. However, as indicated below, the claims remain rejected and the application has yet to be placed in condition for allowance.

Claims 1 and 5 have been cancelled.

Claims 2-4 and 6-27 have been examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 7, 10, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "finlike" renders the claims indefinite because the claims include elements not actually disclosed (those encompassed by "-like"), thereby rendering the scope of the claims unascertainable. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2-4, 6, 7 and 9-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guala (US Patent 5,611,576) in view of Johnson (US Patent 5,702,374).

As to Claims 11 and 14, Guala discloses a luer fitting assembly (Fig 1) comprising a male or female luer fitting member (6) having a longitudinal axis and adapted for connection at a forward end thereof with a female or male luer fitting, respectively, the luer fitting member comprising a restraining surface (3), the restraining surface comprising a rim (adjacent 18) providing an end surface facing distally that is approximately orthogonal to said longitudinal axis; and

a one piece locking member (2) comprising a hollow central lumen, an annular, inwardly protruding plateau shaped protrusion (18) providing an end surface facing proximally that is approximately orthogonal to said longitudinal axis of said lumen (Fig 1), and a body that extends axially beyond at least a portion of the conical restraining surface and toward the forward end of the luer fitting member (Fig 1);

wherein the locking member is capable of, in assembly of the connector assembly, be moved from a rearward end of the luer fitting member toward the forward end thereof (Fig 1), with said protrusion snapping over said conical restraining surface to position said rim end surface and said protrusion end surface to engage each other to

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provide a positive stop against separation of the locking member from the luer fitting member (Fig 1).

However, Guala does not disclose the restraining surface as being conical.

Johnson teaches a similar luer connection having luer fitting member (112) having a conical restraining surface (25) adjacent a rim (24a) to guide and facilitate a snap fit connection of the luer fitting member into a locking member (14; Col 3, Lines 10-24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the luer fitting member of Guala to have a conical restraining surface adjacent a rim as taught by Johnson to guide and facilitate a snap fit connection of the luer fitting member into a locking member.

As to Claims 2, 3, 10, 17 and 18, Guala discloses a luer fitting assembly wherein the locking member comprises a finlike handle and an undulating grip (4; Fig 1).

As to Claims 4 and 19, Guala discloses a luer fitting assembly wherein the locking member comprises a skeletal handle (4, Fig 1; Examiner notes that there are no structural limitations defining what a skeletal handle comprises, and that applicant is merely naming the handle).

As to Claim 6, Guala discloses a luer fitting assembly wherein the locking member (4) comprises a cavity grip having an indentation approximating the shape of a human thumbprint (Fig 1).

As to Claim 7, Guala discloses a luer fitting assembly wherein the finlike handle radially extends outward from approximately one longitudinal end of the locking member (Fig 1).

As to Claim 9, Guala discloses a luer fitting assembly wherein the locking member comprises both a skeletal handle and an undulating grip (Fig 1).

As to Claims 12 and 15, Guala discloses a luer fitting assembly wherein the rim end surface uniformly mates with a corresponding annular surface of the plateau shaped protrusion (Fig 1; Col 2, Lines 15-21).

As to Claims 13 and 16, Guala discloses a luer fitting assembly wherein the rim uniformly mates with a corresponding annular surface of the plateau shaped protrusion (Fig 1; Col 2, Lines 15-21).

As to Claim 20, Guala discloses a luer fitting assembly wherein the locking member is rotatably mounted upon said one of the male or female luer fitting members (Col 2, lines 12-14).

As to Claims 21, 22 and 27, Guala discloses a luer fitting assembly significantly as claimed, but does not disclose wherein said luer fitting member is a male luer fitting member, a female luer fitting member into which said forward end of said male luer fitting member is inserted, said female luer fitting member being connected to said

locking member and wherein said luer fitting member includes a tubular surface forward of said conical restraining surface, and a non-orthogonal surface adjoining said tubular surface generally facing distally.

Johnson teaches a similar luer fitting member being a male luer fitting member (Fig 6) and a female luer fitting member (50) into which said forward end of said male luer fitting member is inserted, said female luer fitting member being connected to said locking member (Fig 7) wherein said luer fitting member includes a tubular surface (60) forward of said conical restraining surface, and a non-orthogonal surface (112) adjoining said tubular surface generally facing distally "to drive the male luer connector into the female luer connector in fluid tight engagement" (Col 3, Lines 26-30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the luer fitting member to be a male member and the locking member to accept a female luer fitting member and for the male member to have tubular and non-orthogonal surfaces extending therefrom to drive the male luer connector into the female luer connector in fluid tight engagement.

As to Claim 23, Guala discloses a luer fitting assembly wherein said rim is adapted to have a clearance fit in said locking member proximally of said protrusion end surface (Col 2, lines 12-14).

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As to Claim 24, Guala discloses a luer fitting assembly wherein said locking member has a rotatable fit with respect to the luer fitting member when said rim is proximal of said protrusion (Col 2, lines 12-14).

As to Claim 25, Guala discloses a luer fitting assembly comprising:

a male or female luer fitting member (6) having a longitudinal axis and adapted for connection at a forward end thereof with a female or male luer fitting, respectively, the luer fitting member comprising a restraining surface (3), the restraining surface comprising a rim providing a distally-facing surface (adjacent 18); and

a one piece locking member (2) comprising a hollow central lumen, an annular, inwardly protruding plateau shaped protrusion (18) providing a proximally-facing surface, and a body that extends axially beyond at least a portion of the conical restraining surface and toward the forward end of the luer fitting member (Fig 1);

wherein the locking member is capable of, in assembly of the connector assembly, being moved from a rearward end of the luer fitting member toward the forward end thereof, with said protrusion snapping over said conical restraining surface, with the locking member having a rotatable fit with respect to the luer fitting member when said rim is proximal of said protrusion; and wherein said proximally-facing surface is adapted in use of the connection to engage said distally-facing surface as a positive stop (Col 2, lines 12-14).

However, Guala does not disclose the restraining surface as being conical.

Johnson teaches a similar luer connection having luer fitting member (112) having a conical restraining surface (25) adjacent a rim (24a) to guide and facilitate a snap fit connection of the luer fitting member into a locking member (14; Col 3, Lines 10-24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the luer fitting member of Guala to have a conical restraining surface adjacent a rim as taught by Johnson to guide and facilitate a snap fit connection of the luer fitting member into a locking member.

As to Claim 26, Guala discloses a luer fitting assembly wherein said locking member (2) extends along said luer fitting member on both sides of said conical restraining surface (Fig 1).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guala view of Werschmidt et al (US Patent 5,620,427)

Guala discloses the luer fitting assembly significantly as claimed, but does not disclose wherein the undulating grip comprises ten waves. Guala does not disclose any structural or functional significance as to the number of undulations on the grip. It has been consistently held that change in the shape of a prior art device is a design consideration within the skill of the art. In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). Accordingly it would have been obvious to one of ordinary skill in the art to modify the assembly of Guala to have the undulating grip comprising ten waves as the reference does not disclose any structural or functional significance as to the

number of undulations on the grip as this is merely a change in shape yielding expected and predictable results.

Response to Arguments

Applicant's arguments with respect to claims 2-4 and 6-25 have been considered but are moot in view of the new ground(s) of rejection.

However, with respect to the Section 112 rejection, contrary to applicant's allegations, the term "finlike" is not used throughout the specification with cross-reference to the drawings. Review of the specification reveals that "finlike" is used at line 1 of page 3 with no reference to any figure and is used at page 4, line 14, without reference to any figure. Further, the specification at page 12, lines 25 and 30-31, makes reference to "no finlike handles" while at page 13, line 5, there is reference to "no solid finlike handles". It is not until page 13, lines 9 and 11, that "finlike" is associated with any structure shown in any figure (122 and 124 in Fig. 10). However, the disclosure at this point makes reference to "solid" finlike handles. Apparently, the term "finlike" encompasses both non-solid and solid structures otherwise "solid" would not have been used directly in front of "finlike". Page 15, lines 15 and 18, refer to "finlike handle 122, 124". Finally, at page 15, lines 15-16, it is disclosed that "finlike" ***may*** have approximately the shape of a dorsal fin of a fish.

Thus, it is evident that the specification carries no written explanation of what "finlike" is supposed to be inclusive of. Further, there is apparently some distinction between "finlike" and "solid finlike". The sole reference to even the type of "fin" that the

term "like" is to modify is not even disclosed until the last page of the specification and this fin type is only described with the permissive language "may" that merely indicates an example, not a requirement. Thus, "finlike" apparently may also include tailfin shapes, pectoral fin shapes, etc.

It is further noted from a comparison of the figures, e.g., see Figs 9 and 10, that the handle actually has the same shape along the outer perimeter thereof. However the handle 86, 88 of Fig. 9 is disclosed as being a "skeletal" handle while the handle 122, 124 of Fig. 10 is disclosed as being a "solid finlike" handle. Accordingly, it is not known and cannot be properly ascertained as to what structure actually constitutes "finlike", whether solid or not, and the specification does not describe any such basis nor does applicant in his remarks. Thus, the handle shown in Fig. 10 is but one, non-limiting, example of a **solid** "finlike" handle.

Nevertheless, it should be noted that while claims are to be read in light of the specification, that does not mean that limitations not in the claims will be read into the claims from the specification. There is nothing in the claims that would reasonably suggest that "finlike" is supposed to be taken as referring to the shape as opposed to any other characteristic of a fin. Notwithstanding what type of shape may constitute a "finlike" shape, if shape is the characteristic desired, then the claims should properly define that such is the case. Note that it is the language of the claims that defines the invention and that there is no provision in utility applications for a claim drawn to "as shown and disclosed". Thus, it is ineffective to seek to rely upon the specification to impart to the claims limitations not otherwise recited therein.

Finally, it has long been held that "-like" renders a claim indefinite when it is not known how a particular element is supposed to resemble (i.e., be "like") the term in question. In the instant case, it is unknown and cannot be properly determined from the claims how a handle that is otherwise not a "fin" is supposed to resemble a fin. Is it to resemble a fin via texture, e.g., by being smooth, scaly, etc., via shape, e.g., pectoral fin, tailfin, dorsal fin, via size, via function, or what? Applicant's remarks appear to imply that one would know that it is based on shape yet "shape" is not indicated in the claims and applicant's own Figs. 9 and 10 illustrate handles having the same external shape but one is skeletal while the other is finlike. Why does not the skeletal handle also constitute a finlike handle? Thus, not only is it not known or defined how a structure is to be like a fin, it is unknown and undefined what shape(s) are encompassed by the term "finlike". See *Ex parte Caldwell*, 1906 C.D. 58 (Comm'r Pat 1906) and MPEP 2173.05(b).

Conclusion

Applicant's amendment, specifically the addition of the limitations of the locking member being made of "one piece" (Claim 11, Line 7; Claim 14, Line 7; Claim 25 Line 6), necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSHUA T. KENNEDY whose telephone number is (571)272-8297. The examiner can normally be reached on M-F: 7am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel P. Stodola can be reached on (571) 272-7087. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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/Joshua T. Kennedy/
Examiner, Art Unit 3679
7/6/2009

/Daniel P. Stodola/
Supervisory Patent Examiner, Art Unit 3679